

TENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 04 May 2001 (04.05.01)	
International application No. PCT/US00/11040	Applicant's or agent's file reference 4590-102WO
International filing date (day/month/year) 24 April 2000 (24.04.00)	Priority date (day/month/year) 23 April 1999 (23.04.99)
Applicant PALACIOS-BOYCE, Monica	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 20 November 2000 (20.11.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Olivia TEFY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

COMMUNICATION IN CASES FOR WHICH
NO OTHER FORM IS APPLICABLE

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

Date of mailing (<i>day/month/year</i>) 22 September 2000 (22.09.00)	
Applicant's or agent's file reference 4590-102WO	REPLY DUE see paragraph 1 below
International application No. PCT/US00/11040	International filing date (<i>day/month/year</i>) 24 April 2000 (24.04.00)
Applicant PALACIOS-BOYCE, Monica	

1. ☐ REPLY DUE within _____ months/days from the above date of mailing
- ☐ NO REPLY DUE, however, see below
- ☒ IMPORTANT COMMUNICATION
- ☐ INFORMATION ONLY

2. COMMUNICATION:

The International Bureau acknowledges receipt of replacement pages 1-94 for the description of the above-mentioned international application and informs the receiving Office that page 17 was not replaced since it was not included in the replacement pages.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
Facsimile No. (41-22) 740.14.35	Telephone No. (41-22) 338.83.38

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/11040**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) :Please See Extra Sheet.

US CL :Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/176, 180, 285.1, 287.2, 288.4, 288.5, 303.1, 305.2, 366, 377, 402, 440, 810; 66/33, 35; 216/39, 43

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 5,961,923 A (NOVA et al.) 05 October 1999, see columns 7-12.	1-41
A	US 5,665,582 A (KAUSCH et al.) 09 September 1997	1,7,14-19
A,P	US 5,968,820 A (ZBOROWSKI et al.) 19 October 1999, see col. 8, lines 21-45.	14-16
A,P	US 6,050,935 A (RANOUX et al.) 18 April 2000, see description of figures.	31-41
Y	US 5,262,128 A (LEIGHTON et al.) 16 November 1993, see entire document.	48-62
A	US 5,114,854 A (BERTHOLDT) 19 May 1992, see entire document.	48-92

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

20 JULY 2000

Date of mailing of the international search report

24 AUG 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DAVID REDDING

Telephone No. (703) 308-0651

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,006,117 A (CASSOU) 09 April 1991, see columns 1-2.	22,23
X	US 5,424,209 A (KEARNEY) 13 June 1995, see entire document.	42,43,46,
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Y		-----
		44,45
A	US 5,863,708 A (ZANZUCCHI et al.) 26 January 1999, see columns 6-8.	17,18,59- 62,93-96, 116,119- 122
A	JORIS, H. et al. Intracytoplasmic sperm injection: laboratory set-up and injection procedure. Human Reproduction Sept. 1, 1998, Vol. 13, pages 76-86.	48-96,99
A	MELDRUM, D.R. et al. Assisted Hatching Reduces the Age-Related Decline in IVF Outcome in Women Younger than Age 43 Without Increasing Miscarriage or Monozygotic Twinning. J. of Assisted Reproduction and Genetics. Vol. 15, No.7, 1998. pages 418-421.	100-103
A	LANZENDORF, S.E. et al. Pregnancy following transfer of ooplasm from cryopreserved-thawed donor oocytes into recipient oocytes. Fertility and Sterility, Vol. 71, No. 3, March 1999. pages 575-577.	104-118, 123-127, 129-131
A	CAMPBELL, K.H.S. et al. Sheep Clones by Nuclear transfer from a cultured cell line. Nature Vol. 380, 7 march 1996, pages 64-66.	104-114, 117,118, 123-127

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (7):

D04B 9/20, 9/00; B23P 15/00; B44C 1/22; C12N 5/00, 5/08, 11/14, 11/08, 15/00; C12M 1/00, 3/00, 1/34, 1/22

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

435/176, 180, 285.1, 287.2, 288.4, 288.5, 303.1, 305.2, 366, 377, 402, 440, 810; 66/33, 35; 216/39, 43

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-21, are drawn to a device for labelling cells.
Group II, claim(s) 22-41, are drawn to a device and method for storing labelled cells.
Group III, claim(s) 42-47, are drawn to device for incubating cells.
Group IV, claim(s) 48-80, are drawn to a device for injecting fluids into cells.
Group V, claim(s) 81-99, are drawn to a device for injecting sperm into a cell.
Group VI, claim(s) 100-103, are drawn to a cell zona coring device.
Group VII, claim(s) 104-131, are drawn to a cell enucleation device.
Group VIII, claim(s) 132-137, are drawn to cell sorting and storing device.

The inventions listed as Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: group I claims are related to an invention for labelling cells; group II claims are related to an invention for holding labelled cells; group III claims related to an invention for the incubation of labelled cells; group IV claims related to an invention for the injection of fluids into cells; group V claims relate to an invention for injecting sperm cells into cells; group VI claims relate to an invention for the zona coring of cells; group VII claims relate to an invention for the enucleation of cells; and group VIII claims relate to an invention for the storing and sorting of cells.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MARY S. KAKEFUDA
MATHEWS, COLLINS, SHEPHERD & GOULD, P.A.
100 THANET CIRCLE SUITE 306
PRINCETON, NJ 08540

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 4590-102WO	Date of Mailing (day/month/year) 24 AUG 2000
International application No. PCT/US00/11040	International filing date (day/month/year) 24 APRIL 2000
Applicant PALACIOS, MONICA BOYCE	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.
Filing of amendments and statement under Article 19:
 The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
 34, chemin des Colombettes
 1211 Geneva 20, Switzerland
 Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:**

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

 Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

 Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DAVID REDDING Telephone No. (703) 308-0651
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 4590-102WO	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US00/11040	International filing date (<i>day/month/year</i>) 24 APRIL 2000	(Earliest) Priority Date (<i>day/month/year</i>) 23 APRIL 1999
Applicant PALACIOS, MONICA BOYCE		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2f

☐ as suggested by the applicant.

☒ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
US00/11040

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

NEW ABSTRACT

The present invention relates generally to microelectromechanical systems (MEMS) devices for the manipulation of cells or groups of cells, such as oocytes, embryos, and sperm. In particular, the present invention relates to Cell Labelling MEMS devices (2F), Microinjection MEMS devices, IntraCytoplasmic Sperm Injection ("ICSI") MEMS devices, Zona Coring MEMS devices, Enucleation MEMS devices, Enucleation/Nuclear Transfer MEMS devices, and Cytoplasmic Transfer MEMS devices. The present invention also relates to kits containing the MEMS devices of the present invention.

INTERNATIONAL SEARCH REPORT

national application No.

US00/11040

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : Please See Extra Sheet.

US CL : Please See Extra Sheet.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/176, 180, 285.1, 287.2, 288.4, 288.5, 303.1, 305.2, 366, 377, 402, 440, 810; 66/33, 35; 216/39, 43

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 5,961,923 A (NOVA et al.) 05 October 1999, see columns 7-12.	1-41
A	US 5,665,582 A (KAUSCH et al.) 09 September 1997	1,7,14-19
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A,P	US 6,050,935 A (RANOUX et al.) 18 April 2000, see description of figures.	31-41
Y	US 5,262,128 A (LEIGHTON et al.) 16 November 1993, see entire document.	48-62
A	US 5,114,854 A (BERTHOLDT) 19 May 1992, see entire document.	48-92



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

20 JULY 2000

Date of mailing of the international search report

24 AUG 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DAVID REDDING

Telephone No. (703) 308-0651

INTERNATIONAL SEARCH REPORT

International application No.

US00/11040

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,006,117 A (CASSOU) 09 April 1991, see columns 1-2.	22,23
X	US 5,424,209 A (KEARNEY) 13 June 1995, see entire document.	42,43,46, 47
----- Y		----- 44,45
A	US 5,863,708 A (ZANZUCCHI et al.) 26 January 1999, see columns 6-8.	17,18,59- 62,93-96, 116,119- 122
A	JORIS, H. et al. Intracytoplasmic sperm injection: laboratory set-up and injection procedure. Human Reproduction Sept. 1, 1998, Vol. 13, pages 76-86.	48-96,99
A	MELDRUM, D.R. et al. Assisted Hatching Reduces the Age-Related Decline in IVF Outcome in Women Younger than Age 43 Without Increasing Miscarriage or Monozygotic Twinning. J. of Assisted Reproduction and Genetics. Vol. 15, No.7, 1998. pages 418-421.	100-103
A	LANZENDORF, S.E. et al. Pregnancy following transfer of ooplasm from cryopreserved-thawed donor oocytes into recipient oocytes. Fertility and Sterility, Vol. 71, No. 3, March 1999. pages 575-577.	104-118, 123-127, 129-131
A	CAMPBELL, K.H.S. et al. Sheep Clones by Nuclear transfer from a cultured cell line. Nature Vol. 380, 7 march 1996, pages 64-66.	104-114, 117,118, 123-127

A. CLASSIFICATION OF SUBJECT MATTER:

IPC (7):

D04B 9/20, 9/00; B23P 15/00; B44C 1/22; C12N 5/00, 5/08, 11/14, 11/08, 15/00; C12M 1/00, 3/00, 1/34, 1/22

A. CLASSIFICATION OF SUBJECT MATTER:

US CL :

435/176, 180, 285.1, 287.2, 288.4, 288.5, 303.1, 305.2, 366, 377, 402, 440, 810; 66/33, 35; 216/39, 43

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-21, are drawn to a device for labelling cells.

Group II, claim(s) 22-41, are drawn to a device and method for storing labelled cells.

Group III, claim(s) 42-47, are drawn to device for incubating cells.

Group IV, claim(s) 48-80, are drawn to a device for injecting fluids into cells.

Group V, claim(s) 81-99, are drawn to a device for injecting sperm into a cell.

Group VI, claim(s) 100-103, are drawn to a cell zona coring device.

Group VII, claim(s) 104-131, are drawn to a cell enucleation device.

Group VIII, claim(s) 132-137, are drawn to cell sorting and storing device.

The inventions listed as Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: group I claims are related to an invention for labelling cells; group II claims are related to an invention for holding labelled cells; group III claims related to an invention for the incubation of labelled cells; group IV claims related to an invention for the injection of fluids into cells; group V claims relate to an invention for injecting sperm cells into cells; group VI claims relate to an invention for the zona coring of cells; group VII claims relate to an invention for the enucleation of cells; and group VIII claims relate to an invention for the storing and sorting of cells.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

14

REC'D 20 NOV 2001

WIPO PCT

Applicant's or agent's file reference 4590-102WO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US00/11040	International filing date (day/month/year) 24 APRIL 2000	Priority date (day/month/year) 23 APRIL 1999
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant PALACIOS-BOYCE, MONICA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 20 NOVEMBER 2000	Date of completion of this report 08 OCTOBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer DAVID REDDING
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0651

I. Basis of the report**1. With regard to the elements of the international application: ***☒ the international application as originally filed☒ the description:pages 1-94 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____☒ the claims:pages 95-118 , as originally filedpages NONE , as amended (together with any statement) under Article 19pages NONE , filed with the demandpages NONE , filed with the letter of _____☒ the drawings:pages 1-33 , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____☒ the sequence listing part of the description:pages NONE , as originally filedpages NONE , filed with the demandpages NONE , filed with the letter of _____**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages None☒ the claims, Nos. None☒ the drawings, sheets/fig None**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

Please See Supplemental Sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)	Claims <u>1-137</u>	YES
	Claims <u>None</u>	NO
Inventive Step (IS)	Claims <u>1-137</u>	YES
	Claims <u>None</u>	NO
Industrial Applicability (IA)	Claims <u>1-137</u>	YES
	Claims <u>None</u>	NO

2. citations and explanations (Rule 70.7)

Claims 1-137 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest (1) a cell labeling MEMS device comprising a plurality of wells comprising a labelable zona anchor MEMS device or method of making such a device; (2) a labelable zona anchor MEMS device comprising at least one anchor and a labelable surface for receiving a label; (3) a cell labeling MEMS device comprising a substrate comprising at least one well and each well having at least one labelable zona anchor MEMS device; (4) a cell labelling MEMS kit comprising a platter having an outer edge and a plurality of grooves, arranged in a concentric pattern on the surface, and at least one cell labeling MEMS device attached to the outer edge of the platter and the method of using the kit; (5) a labelable zona anchor MEMS device platform holder comprising an inner cylinder comprising securing means for securing a labelable zona anchor MEMS device platform to the holder; (6) an automated multi-compartment, multi modal incubator for incubating cells or group of cells that are attached to a labelable zona anchor MEMS device platform comprising a block having a plurality of compartments capable of receiving a labelable zona anchor MEMS device platform; (7) a microinjection MEMS device for injecting a fluid into a cell comprising a substrate comprising a well having at least one hollow protuberance for penetrating the cell, and method of making the device, kit thereof or method of using the device; (the wells of USP 5,262,128 do not have protuberances, they are provided by the input manifold (22)); (8) an Intracytoplasmic Sperm Injection MEMS array comprising a substrate comprising at least one well having a hollow protuberance for penetrating a cell and a sperm handling manifold, method of using the device or method of making the device; (9) a sperm guillotine mechanism comprising an enclosed channel for containing sperm, a first and second guillotine enclosing each end of the channel, method of making the mechanism; (10) a zona coring MEMS device for forming one or more cores in the zona pellucida of a cell comprising a substrate having a plurality of wells with each well having a coring member or method of making or using the device; (11) an enucleation MEMS device for enucleating a cell comprising at least one well for holding a cell wherein the well comprises (Continued on Supplemental Sheet.)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): D04B 9/20, 9/00; B23P 15/00; B44C 1/22; C12N 5/00, 5/08, 11/14, 11/08, 15/00; C12M 1/00, 3/00, 1/34, 1/22
and US Cl.: 435/176, 180, 285.1, 287.2, 288.4, 288.5, 303.1, 305.2, 366, 377, 402, 440, 810; 66/33, 35; 216/39, 43 ;
935/85

IV. LACK OF UNITY OF INVENTION:

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2, and 13.3 is not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-21, are drawn to a device for labelling cells.
Group II, claims 21-41, are drawn to a method and device for storing labelled cells.
Group III, claims 42-47, are drawn to a device for incubating cells.
Group IV, claims 48-80, are drawn to a device for injecting fluids into cells.
Group V, claims 81-99, are drawn to a device for injecting sperm into a cell.
Group VI, claims 100-103, are drawn to a cell zona coring device.
Group VII, claims 104-131, are drawn to a cell enucleation device.
Group VIII, claims 132-137, are drawn to a cell sorting and storing device

The inventions listed as Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: group I claims are related to an invention for labelling cells; group II claims are related to an invention for holding cells; group III claims are related to an invention for the incubation of labelled cells; group V claims relate to an invention for injecting sperm cells into cells; group VI claims relate to an invention for the zona coring of cells; group VII claims related to an invention for enucleation of cells, and group VIII claims relate to an invention for storing and sorting of cells.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

an enucleation penetration member and an enucleation pit for isolating the nucleus of the cell or method of using the device;
(12) a Cytoplasmic transfer MEMS device comprising at least one well having a hollow protuberance and an extraction siphon in fluid communication with the hollow protuberance; (13) a multi-layer cell culture MEMS array comprising a multi-laminate planar layer comprising at least one movement track attractive to labelable zona anchor MEMS device attached to the enclosed channel.

----- NEW CITATIONS -----

NONE